REMARKS

The present document is submitted in response to the Final Office Action dated April 8, 2008 ("Office Action").

Initially, Applicant would like to thank the Examiner and the Supervisory Examiner for granting the telephone interview with Applicant's counsel held on May 13, 2008. A summary of the interview is provided below.

Applicant has amended claim 1 to more particularly and specifically point out the subject matter that Applicant deems as his invention. This amendment has necessitated cancellation of claim 5. No new matter has been introduced.

The amendment should be entered as it raises no new issues that will require further consideration or search and also does not touch the merits of the application within the meaning of 37 C.F.R. § 1.116(b).

Upon entry of the amendment, claims 1, 11, and 14-17 will be under examination. Applicant respectfully requests that the Examiner reconsider this application in view of the following remarks.

Interview Summary

On May 9, 2008, Applicant's counsel sent a letter via facsimile to the Examiner, outlining arguments to be discussed during the interview scheduled for May 13, 2008. More specifically, Applicant's counsel pointed out that the claims under examination are directed to treating certain side effects associated with chemo- or radio-therapy, not to cancer therapy as the Examiner believed.

At the beginning of the interview, the Supervisory Examiner stated that, after considering the letter, he agreed to withdraw the lack-of-enablement and lack-of-written-description rejections.

Turning to the rejection for obviousness, the Examiner argued that all of the claims under examination are obvious over the anti-cancer methods taught in Samid, US Patent No. 5,877,213 ("Samid") and Shufeng et al. Investigational New Drugs, 20:281-295 (2002) ("Shufeng"). More specifically, the Examiner is of the position that the

treatment covered by the rejected claims and the methods taught in the two references can all be applied to the same patient population, i.e., cancer patients. Applicant's counsel presented counter-arguments, which are submitted at page 9 below. Applicant's counsel also proposed to delete from claim 1 the phrase "for proliferating malignant or nonmalignant disease" to make it clear that this claim does not cover treating any malignant disease (i.e., cancer). Both the Examiner and the Supervisory Examiner agreed to reconsider this application upon receipt of Applicant's written presentation of the proposed amendment and arguments, both of which are submitted herein.

Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1, 5, 11, and 14-17 are rejected for lack of enablement. See the Office Action, page 2. More specifically, the Examiner asserts that "there is a lack of support in the disclosure for the treatment of all **cancerous tumors**." See the Office Action, page 3, first paragraph; emphasis added. Applicant respectfully disagrees.

Independent claim 1 will be discussed first. This claim, as amended, covers a method for increasing **therapeutic gain** in chemo- or radio-therapy. The term "**therapeutic gain**" is defined in claim 1 as achieving the following three therapeutic goals: (i) ameliorating complications induced by chemo- or radio-therapy, (ii) protecting normal tissues from cell death (resulting from chemo- or radio-therapy), and (iii) promoting radiation-induced would healing. All of the three therapeutic goals aim at treating certain side effects induced by chemo- or radio-therapy. Reciting these therapeutic goals, amended claim 1 clearly aims at treating the side effects induced by chemo- or radio-therapy. In other words, this claim, as amended, clearly does not cover cancer treatment as believed by the Examiner.

Applicant has submitted the above arguments to the Examiner in the letter mentioned in the "Interview Summary" section, supra. As pointed out in the same section, the Supervisory Examiner agreed during the interview that this rejection would be withdrawn if Applicant would amend claim 1 to replace the term "preventing" recited therein with "ameliorating." Applicant has made the proposed amendment.

It is submitted that claim 1, as amended, meets the enablement requirement. As claims 11, 14-17, all dependent from claim 1, are rejected on the same ground, they also satisfy this requirement. Claim 5, the remaining rejected claim, has been cancelled.

Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner rejects claims 1, 5, 11, and 14-17 for lack of written description on the ground that "[n]o mechanism of action or data is provided to support Applicant's claim for **preventing** complications or sequelae of a disorder, both of which are induced by radiation or chemotherapy."[1] See the Office Action, page 7; emphasis added.

Applicant has replaced the term "preventing" recited in claim 1 with "ameliorating." As the Examiner agreed in the telephone interview (see the "Interview Summary" section, supra), this amendment has overcome the rejection.

Rejection under 35 U.S.C. § 103

The Examiner rejects all of the claims under examination for obviousness on two grounds, which are addressed separately below:

I

Claims 1, 5, 11, and 14-16 are rejected for obviousness over Samid. See the Office Action, page 7, last paragraph. Note that claim 5 has been cancelled.

As discussed above, amended claim 1 covers ameliorating certain side effects induced by chemo- or radio-therapy by administering a histone hyperacetylating agent to a subject in need of this treatment.

Samid teaches a method of using a histone hyperacetylating agent, i.e., phenylacetate, for treating **anemia, cancer**, **AIDS**, or **severe β-chain hemoglobinopathies,** none of which is relevant to any side effects induced by chemo/radio-therapy.

[1] Given the Examiner's ground for rejection as quoted above, Applicant would like to point out that she should have rejected these claims for lack of enablement (which she already did), not for lack of written description. In any event, Applicant submits that the reject claims, as amended, meet both the written description and enablement requirements.

Applicant would like to first point out that, to support this rejection, the Examiner relies on an incorrect interpretation of the rejected claims; namely, they cover cancer treatment (see the Office Action page 7, line 14 through page 8, line 20). For the reasons set forth at page 7, supra, and agreed by the Examiner (see the "Interview Summary" section, supra), the rejected claims are indeed directed to ameliorating certain side effects induced by chemo- or radio-therapy, but not directed to treating cancer. In addition, Applicant has removed the phrase "for proliferating **malignant** or nonmalignant disease" from claim 1 to make it clearer that this claim and its dependent claims do not cover treating **cancer** (i.e., **malignant disease**). Thus, given the erroneous claim interpretation, the Examiner's ground for rejection is clearly invalid.

Applicant next address the Examiner's ground asserted during the interview (see the "Interview Summary" section, supra), using claim 1 as an example.

The Examiner contended that, as both the method of amended claim 1 and the Samid method can be applied to cancer patients, the claimed method is obvious over Samid. Applicant respectfully disagrees.

As pointed out above, the method of claim 1, aiming at reducing chemo/radio-therapy induced side effects in a subject, requires administering a histone hyperacetylating agent to the subject in need thereof. More specifically, the claimed method targets subjects (e.g., cancer patients) who suffer from certain side effects induced by chemo- or radio-therapy. Accordingly, a skilled person in the art would readily know that this method requires first **identifying a subject suffering from chemo- or radio-therapy induced side effects**.

Samid teaches a method of using a histone hyperacetylating agent for treating cancer. As this reference does not suggest that the agent would be effective in reducing chemo/radio-therapy induced side effects, it clearly also does not suggest administering the agent to a cancer patient who has developed chemo/radio therapy-induced side effects, let alone identifying such a patient as required by the claimed method.

In view of the above remarks, Applicant submits that Samid does not render claim 1 obvious. Nor does it render obvious claims 11 and 14-16, all of which depend from claim 1.

II

Claims 1 and 17 are rejected as obvious over Samid in view of Shufeng. Applicant respectfully disagrees.

These two claims cover methods for ameliorating certain side effects induced by chemo- or radio- therapy with a histone hyperacetylating agent.

Samid has been discussed above. Shufeng discloses the anti-cancer effect of DMXAA, a histone hyperacetylating agent. The same as Samid, this reference also does not suggest using any histone hyperacetylating agent for ameliorating chemo/radio therapy induced side effects, let along identifying a cancer patient suffering from chemo- or radio-therapy induced side effects. Thus, for the same reason as set forth at page 9, supra, these two references, in combination, do not render obvious claims 1 and 17, which depends from claim 1.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment.

In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

No fee is believed to be due. Please apply any charges to Deposit Account No. 50-4189, referencing Attorney Docket No. 55701-004002.

Respectfully submitted,

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